

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/971,960	11/17/97	STILZ	H 026083/0138

FOLEY & LARDNER
SUITE 500
3000 K STREET N W
P O BOX 25696
WASHINGTON DC 20007

HM12/0726

EXAMINER	
QAZI, S	
ART UNIT	PAPER NUMBER
1616	20
DATE MAILED: 07/26/01	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/971,960

Applicant(s)
Stilz et al.

Examiner
Sabiha N. Qazi

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 21, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-24 and 39-103 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24 and 39-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Art Unit: 1616

Office Action on Merits

Status of the application

Claims 21-24 and 39-103 are pending.

Claims 21-24 and 39-103 are rejected.

No claim is allowed.

Applicant's amendments filed in paper no. 27, dated 5/21/01 is hereby acknowledged. Amendments are entered. Rejections under 112 (2) and 112(1) mailed in paper no. 24 are withdrawn because claims are amended.

A Double Patenting rejection is made because there is a copending application 09/405,843 and US Patent 5,998,447 containing the same subject matter as instantly claimed and was not did not disclosed by the Applicants.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1616

1. Claims 21-24 and 39-103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Because of the high level of unpredictability associated with treatment or disorder of tumor growth or tumor metastasis a greater amount of evidentiary support is needed in order to fully satisfy the requirement of 35 USC 112, first paragraph, that applicants provide sufficient guidance as regards "how to use" the invention. There is no evidence in specification anywhere that any testing protocol was used for the alleged utility. In claim 23 "tumor growth" and "tumor metastasis" are generic terms that embrace many different diseases such as leukemia.

There is no drug which is broadly effective against all forms of tumors, (see Carter S.K. et al. Chemotherapy of Cancer, pages 364 and 365; second edition, John Wiley & sons, New York, 1981, appendix C). See table on pages 364 and 365 where the interaction of different drugs on various type of cancer are listed. It is clear from the data that each drug has different

Art Unit: 1616

interactions with different types of tumors i.e. one drug cannot treat all type of tumors. Applicant need to point out in the specification where there is a support including pharmacological data for treating specific type of tumors. A mere statement does not provide enabling support for such a utility. If there is any support of tumors, the claims must be limited to such type of tumors. Similarly for all the specific diseases in claimed must be limited. As is known that there is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970).

Since claim are broad and since there is a lack of a guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1616

Claims 21-24 and 39-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Inflammatory disorder of central nervous system", "which can also contain", "can optionally be", "can optionally stand", "which can also be substituted", which can also contain" "forms and mixtures" (should be "forms or mixtures"), "and/or", "cannot all simultaneously be", "customary in peptide chemistry", "can be protected", "free functional groups", "allergies", "which can contain", "can be", renders claims indefinite because there no limits and boundaries on claims.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1616

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 21-24 and 39-103 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-20 of copending Application No. 09/405,843. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

For instance instant claim 22 is drawn to a method for antagonizing VLA-4 and the same invention is claimed in claim 1 of copending application

The method of treatment as instantly claimed are obvious/overlap the claims of the said copending application.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the

Art Unit: 1616

instant application in the other copending application. See *In*
See also MPEP § 804.

3. Claims 21-24 and 39-103 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 09/405,843. Although the conflicting claims are not identical, they are not patentably distinct from each other because Instantly claimed method of treatment or disorder widely overlaps with the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Search was limited to elected invention of group II, others were withdrawn from consideration as non elected invention. In order to advance prosecution Applicant is requested to amend the claims while responding to this action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can

Serial Number: 08/971,960

Page 8

Art Unit: 1616

normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

7/25/01



**SABIHA QAZI, PH.D
PRIMARY EXAMINER**